K013659

DEC 0 6 2001

Special 510(k) Summary
for
SIDEXIS Digital Radiography Imaging System

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 3294

Date Prepared: November 5, 2001

2. DEVICE NAME

Proprietary Name: SIDEXIS Digital Radiography Imaging System
Common/Usual Name: Digital X-ray Imaging System
Classification Name: Accessory to Extraoral Source X-ray System

3. PREDICATE DEVICE

SIDEXIS Digital Radiography System –K992644

4. INTENDED USE

The SIDEXIS is a digital imaging system intended to replace conventional radiographic film for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

5. DEVICE DESCRIPTION

SIDEXIS consists of intraoral and extraoral digital X-ray sensors, image acquisition boards, and software to be installed into an IBM-compatible personal computer. This

Special 510(k) is being submitted to document a new sensor and associated software for digital transverse slice imaging in conjunction with the Orthophos Plus DS / Plus DS Ceph family of digital extraoral source X-ray imaging devices. Other minor modifications discussed in this Special 510(k) include: 1) a new XAB image acquisition board to interface SIDEXIS to the Orthophos X-ray systems via the Ethernet; 2) a new USB (Universal Serial Bus) Box to interface the SIDEXIS with the intraoral sensors; and 3) software enhancements to improve the overall function of SIDEXIS (resulting in software version 5.5).

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The SIDEXIS system that is the subject of this 510(k) premarket notification is a modification of SIDEXIS as previously cleared for marketing under K992644. The modified SIDEXIS has the same intended use and principles of operation as the original SIDEXIS, as well as substantially equivalent technical specifications. A hazard analysis, validation testing, and Declaration of Conformity to Design Controls were submitted to support the substantial equivalence of the modified SIDEXIS Digital Radiography Imaging System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Sirona Dental Systems, Inc.
% Ms. Sheila M. Hemeion-Heyer
Medical Device Consultants
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K013659
Trade/Device Name: SIDEXIS Digital Radiography Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: November 5, 2001
Received: November 6, 2001

Dear Ms. Hemeion-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: SIDEXIS DIGITAL RADIOGRAPHY IMAGING SYSTEM

Indications For Use:

SIDEXIS is a digital radiography imaging system intended to replace conventional radiographic film for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Degerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013059

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)